

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW  
YORK, by LETITIA JAMES, Attorney  
General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING  
COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited  
liability company;

PREVAGEN, INC., a corporation  
d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE  
MANUFACTURING, LLC, a limited  
liability company; and

MARK UNDERWOOD, individually and as  
an officer of QUINCY BIOSCIENCE  
HOLDING COMPANY, INC., QUINCY  
BIOSCIENCE, LLC, and PREVAGEN,  
INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

**PLAINTIFFS' TRIAL BRIEF AND  
LIST OF INDIVIDUALS AND  
COMPANIES THAT MAY BE  
WITNESSES OR REFERRED TO AT  
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Plaintiffs, the Federal Trade Commission (“FTC”) and the People of the State of New York by Letitia James, Attorney General of the State of New York (“NYAG”), respectfully submit this trial brief and list of individuals or companies that may be witnesses or referred to at trial, pursuant to the Court’s Order dated August 2, 2022 (ECF No. 289).

## **I. INTRODUCTION**

Plaintiffs allege that Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc, Quincy Bioscience Manufacturing, LLC (collectively “Corporate Defendants”), and Mark Underwood, have engaged in deceptive advertising for Prevagen, which contains apoaequorin, a synthetic protein originally derived from jellyfish, and since 2016, Vitamin D. Since 2007, Defendants have advertised to consumers, including on national television, that Prevagen improves memory and provides other cognitive benefits, while touting their randomized clinical trial (“RCT”), the Madison Memory Study, as support for their advertising claims. Defendants lack support for these claims. Neither the Madison Memory Study—which was not well-designed, was not double-blinded, had no statistically significant results in the study’s total population, and touted results from flawed *post hoc* subgroup analyses—nor Defendants’ other evidence, shows that Prevagen improves memory or provides other cognitive benefits. Defendants’ later use of qualifying language in their advertising in 2020, as required by a settlement agreement in *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864-MGC (S.D. Fla.) (the “Collins Qualifier” or “Qualifier”), is of no consequence. Not only is the Collins Qualifier not clear or conspicuous, but Defendants continue to lack support for their claims that Prevagen improves memory and provides other cognitive benefits. Because Defendants’ false or unsubstantiated advertising claims were likely to mislead reasonable consumers and were unquestionably material to consumers under the law, Corporate Defendants, acting as a common enterprise, are all liable for violating the FTC Act and New York General

Business Law §§ 349 and 350. Because Defendants’ false or unsubstantiated advertising claims had the capacity or tendency to deceive credulous consumers, Corporate Defendants are also liable for violating New York Executive Law § 63(12). Moreover, Mr. Underwood, who participated in the deceptive practices and controlled the Corporate Defendants, is individually liable for violating the FTC Act. Injunctive relief, with fencing in, is warranted, especially since Defendants continued to widely advertise their health claims despite having been aware of the deceptive nature of those claims for many years. The NYAG is also entitled to restitution, disgorgement, statutory penalties, and costs for Corporate Defendants’ violations of New York law.

In their trial brief, Plaintiffs also address other legal issues, including that Plaintiffs have applied the appropriate substantiation standard, FDA laws are inapplicable, testimony of Defendants’ experts should be excluded, consumer testimonials are not competent and reliable scientific evidence, deceptive commercial speech has no constitutional protection, and satisfied consumers or a lack of consumer complaints are not defenses to liability under the FTC Act. Plaintiffs further address several of Defendants’ meritless objections to Plaintiffs’ exhibits, as well as a number of Defendants’ inadmissible exhibits. Defendants, for example, have objected on hearsay grounds to many of their own documents, including their Answers to the Complaint and emails of their employees. Such documents, and statements within them, however, are either judicial admissions or statements of a party opponent. Defendants also have proffered numerous inadmissible exhibits, including their own experts’ reports, which are hearsay, and irrelevant documents relating to prescription drugs and the FDA.<sup>1</sup>

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<sup>1</sup> Plaintiffs may file motions in limine prior to trial, including ones related to the issues raised in this brief.

## II. DEFENDANTS HAVE VIOLATED THE FTC ACT

Section 5 of the FTC Act prohibits “deceptive acts or practices in or affecting commerce.” 15 U.S.C. § 45(a); *FTC v. Med. Billers Network, Inc.*, 543 F. Supp. 2d 283, 303 (S.D.N.Y. 2008). To establish liability under Section 5, “the FTC must show three elements: ‘[1] a representation, omission, or practice, that [2] is likely to mislead consumers acting reasonably under the circumstances, and [3], the representation, omission, or practice is material.’” *FTC v. LeadClick Media*, 838 F.3d 158, 168 (2d Cir. 2016) (quoting *FTC v. Verity Int’l*, 443 F.3d 48, 63 (2d Cir. 2006)); *see also* *FTC v. Moses*, 913 F.3d 297, 306-07 (2d Cir. 2019).

Section 12 of the FTC Act makes it unlawful for any person or corporation to disseminate, or cause to be disseminated, any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of foods, drugs, devices, or cosmetics. 15 U.S.C. § 52; *FTC v. COORGA Nutraceuticals*, 201 F. Supp. 3d 1300, 1308 (D. Wyo. 2016). A “false advertisement” means an advertisement which is “misleading in a material respect.” 15 U.S.C. § 55(a)(1). False advertising in violation of Section 12 is a deceptive act or practice in violation of Section 5. 15 U.S.C. § 52(b); *see also* *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 7–8 (1st Cir. 2010) (noting that Sections 5 and 12 of the FTC Act are applied in tandem as the basis for deceptive advertising claims).

The FTC does not need to show evidence of an intent to deceive consumers to establish a violation. *Verity Int’l*, 443 F.3d at 63. Good faith is also not a defense to liability. *FTC v. Quincy Bioscience Holding Co.*, No. 17-cv-124-LLS, 2020 WL 1031271, at \*3 (S.D.N.Y. Mar. 2, 2020) (stating that good faith is not relevant to determining whether Defendants engaged in deceptive advertising practices).

Defendants have advertised for years that Prevagen improves memory and provides other cognitive benefits, and that such benefits were based on an RCT, the Madison Memory Study. Because the Madison Memory Study's analysis was flawed and thus unreliable, and Defendants' other scientific evidence is insufficient, Defendants' claims that Prevagen improves memory and provides other cognitive benefits are likely to mislead reasonable consumers and are presumed to be material under the law. Therefore, Defendants have violated the FTC Act.

**a. Defendants Advertised that Prevagen Improves Memory and Provides Other Cognitive Benefits**

In determining whether an advertisement conveys a claim, the jury should look at the overall, net impression created by the advertisement, through the interaction of different elements in the advertisement, rather than focusing on the individual elements in isolation. *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 687-88 (3d Cir. 1982); *see also FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) (“The entire mosaic should be viewed rather than each tile separately. ‘The buying public does not ordinarily carefully study or weigh each word in an advertisement. . . .’” (quoting *Aronberg v. FTC*, 132 F.2d 165, 167 (7th Cir. 1942))). A fact finder focuses on the “overall impression created by the advertising, not its literal truth or falsity.” *Med. Billers Network, Inc.*, 543 F. Supp. 2d at 304 (internal quotation marks omitted) (citing *Sterling Drug, Inc.*, 317 F.2d at 675, which stated that an advertisement “as a whole may be completely misleading although every sentence separately considered is literally true”). “The alleged misrepresentations should be evaluated as a whole without emphasizing isolated words or phrases apart from their context.” *Med. Billers Network, Inc.*, 543 F. Supp. 2d at 304 (internal quotation marks omitted). “[E]ach representation must stand on its own merit, even if other representations contain accurate, non-deceptive information.” *Id.* (internal quotation marks omitted). “[S]tatements susceptible of both a misleading and a truthful interpretation will be

construed against the advertiser.” *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 127 n.6 (D. Conn. 2008) (quoting *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964)); *see also Fanning v. FTC*, 821 F.3d 164, 171 (1st Cir. 2016) (noting that “a seller is liable for the misleading interpretation even if nonmisleading interpretations are possible”).

An advertisement can make express or implied claims. “Express claims directly represent the fact at issue while implied claims do so in an oblique or indirect way.” *Kraft, Inc. v. FTC*, 970 F.2d 311, 318 n.4 (7th Cir. 1992). If an advertisement makes a claim expressly, then extrinsic evidence about what claims were conveyed to consumers is not necessary. *Id.* at 318. Additionally, extrinsic evidence is unnecessary for an implied claim “as long as those claims are reasonably clear from the face of the advertisement.” *Bronson Partners, LLC*, 564 F. Supp. 2d at 126, 128 (finding that no extrinsic evidence was necessary where the advertisement’s statements were “so clear, repetitive, and unambiguous that they constitute[d] the functional equivalent of express claims”); *FTC v. Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008) (“If the advertisement explicitly states or clearly and conspicuously implies a claim, the court need not look to extrinsic evidence to ascertain whether the advertisement made the claim.”); *FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 958 (N.D. Ill. 2006) (stating that implied claims “fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernable” and “[i]t is only at the latter end of the continuum that extrinsic evidence is necessary” (internal quotation marks omitted)).

Whether an advertisement is likely to mislead consumers acting reasonably under the circumstances is evaluated from the perspective of the reasonable consumer in the audience targeted by the advertiser. *FTC v. Fleetcor Techs., Inc.*, No. 1:19-cv-5727-AT, 2022 WL 3273286, at \*6 (N.D. Ga. Aug. 9, 2022); *FTC v. Washington Data Res.*, 856 F. Supp. 2d 1247,



1272 (M.D. Fla. 2012) (stating that “advertising deception is evaluated from the perspective of the reasonable purchaser, that is a reasonable consumer in the audience targeted by the advertisement”). An advertisement can be misleading if at least a significant minority of reasonable consumers would be likely to take away the misleading claim. *Fanning*, 821 F.3d at 171.

Based on the net impression, Defendants’ advertisements have expressly claimed, and continue to claim, that Prevagen: (1) improves memory, (2) improves memory within 90 days, (3) reduces memory problems associated with aging, and (4) provides other cognitive benefits, including healthy brain function, a sharper mind, and clearer thinking (collectively “Challenged Health Efficacy Claims”). Defendants have also expressly touted to consumers that Prevagen is clinically shown, primarily based on the Madison Memory Study, to: (1) improve memory, (2) improve memory within 90 days, (3) reduce memory problems associated with aging, and (4) provide other cognitive benefits, including healthy brain function, a sharper mind, and clearer thinking (collectively “Challenged Establishment Claims”).

**b. Challenged Health Efficacy Claims Were Unsubstantiated**

The FTC can prove that a representation is likely to mislead consumers by showing that an advertiser lacks a reasonable basis to substantiate a claim at the time of dissemination. *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 491 (D.C. Cir. 2015); *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309. “An efficacy claim suggests that a product successfully performs the advertised function or yields the advertised benefit, but includes no suggestion of scientific proof of the product’s effectiveness.” *POM Wonderful*, 777 F.3d at 490. What constitutes a reasonable basis can depend on multiple factors, including the type of claim and product, consequences of a false claim, benefits of a truthful claim, ease of developing substantiation for

the claim, and the amount of substantiation experts in the field would consider reasonable. *POM Wonderful*, 777 F.3d at 490-91.

For health efficacy claims, such as those alleged in Count I of the Complaint, courts have interpreted the reasonable basis requirement to mean competent and reliable scientific evidence. *See, e.g., FTC v. NPB Adver., Inc.*, 218 F. Supp. 3d 1352, 1358 (M.D. Fla. 2016); *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1202; *QT, Inc.*, 448 F. Supp. 2d at 961; *see also Bristol-Myers Co. v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984) (upholding an order defining reasonable basis to consist of competent and reliable scientific evidence). “[T]he ‘competent and reliable scientific evidence’ standard is one which has been developed over many years by agency enforcement precedent and guidance from the FTC.” *Direct Mktg. Concepts, Inc. v. FTC*, 581 F. Supp. 2d 115, 118 (D. Mass. 2008). To determine what constitutes competent and reliable scientific evidence, courts regularly look to experts in the relevant field. *See, e.g., Daniel Chapter One v. FTC*, 405 F. App’x 505, 506 (D.C. Cir. 2010); *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309; *FTC v. Alcoholism Cure Corp.*, No. 3:10-cv-266-J-34JTB, 2011 WL 13137951, at \*27 (M.D. Fla. Sept. 16, 2011) (“The Court can look to what experts in the relevant area of study would consider to be adequate in determining the amount and type of evidence that is sufficient for scientific validation of the advertisement’s claims.” (quotation marks omitted)). This standard “is context specific and permits different variations . . . depending on what pertinent professionals would require for the particular claim made.” *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1186.

Courts have regularly applied the competent and reliable scientific evidence standard and concluded that an RCT was required to substantiate health claims based on expert evidence, including for dietary supplements. *See, e.g., POM Wonderful*, 777 F.3d at 505; *Daniel Chapter*

*One*, 405 F. App'x at 506 (noting that there was nothing “unreasonable about the specific type of basis required by the Commission, namely, ‘competent and reliable scientific evidence’ including clinical trials with human subjects”); *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1387-89 (M.D. Fla. 2018); *NPB Adver., Inc.*, 218 F. Supp. 3d at 1359; *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309 (finding that an RCT is the requisite level of substantiation); *Alcoholism Cure Corp.*, 2011 WL 13137951, at \*39 (noting that many courts have “embrac[ed] the placebo-controlled, double-blind clinical study as the most basic and fundamental requirement for scientific validity and reliability to support health-related claims (including dietary supplements)”); *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1202; *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 303-04 (D. Mass. 2008) (stating that it is “well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims”); *FTC v. Braswell*, No. CV 03-3700, 2005 WL 4227194, at \*10 (C.D. Cal. Sept. 27, 2005) (listing cases where “courts . . . have found or upheld that double-blind, placebo controlled studies are required to provide adequate substantiation for various efficacy claims, including claims for dietary supplements”).

Defendants are required to have substantiation for their advertising claims prior to making them and have the burden of establishing what substantiation they relied on. *FTC v. John Beck Amazing Profits, LLC*, 865 F. Supp. 2d 1052, 1067 (C.D. Cal. 2012); *Alcoholism Cure Corp.*, 2011 WL 13137951, at \*26. The FTC has the burden of proving that Defendants' substantiation is inadequate. *Alcoholism Cure Corp.*, 2011 WL 13137951, at \*26. Contrary to Defendants' assertions, the FTC does not have to conduct or present clinical studies showing that the product does not work as claimed. *Id.*

Plaintiffs’ expert in the relevant scientific fields—memory, cognition, and clinical trials—will testify that in order to substantiate the Challenged Health Efficacy Claims, one would need a well-conducted RCT that yields statistically significant and clinically meaningful results. Based on procedures generally accepted in the relevant fields to yield accurate and reliable results, Defendants’ RCT, the Madison Memory Study, was not well-designed, was not double-blinded, had no statistically significant results for its entire population, and its subgroup results, which were not prespecified before the study started, do not support conclusions about Prevagen’s efficacy. Furthermore, Defendants’ cited Vitamin D literature and non-RCT research—open-label studies and studies in laboratories, dogs, rats, and humans—do not substantiate their claims regarding Prevagen, and in many instances, when taken as a whole, refute Defendants’ claims.

**c. Challenged Establishment Claims Were False**

The FTC can also prove that a representation is likely to mislead consumers by showing that the representation is in fact false. *Id.* at \*26. Claims that identify a specific type of substantiation, like those alleged in Count II of the Complaint, are establishment claims, and Defendants must have the level of evidence touted repeatedly in their own advertisements—evidence from an RCT—to support the Challenged Establishment Claims. *Roca Labs, Inc.*, 345 F. Supp. 3d at 1381, 1388 (noting that an establishment claim is required to have the level of proof claimed in the ad); *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309 (“If an establishment claim ‘states a specific type of substantiation,’ the ‘advertiser must possess the specific substantiation claimed.’” (quoting *Removatron Int’l Corp. v. FTC*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989))); *FTC v. Wellness Support Network*, No. 10-cv-04879-JCS, 2014 WL 644749, at \*16 (N.D. Cal. Feb. 19, 2014) (finding that “for establishment claims advertisers must have the level of substantiation referenced in the claim itself”). Otherwise, the Challenged

Establishment Claims are false. *Wellness Support Network*, 2014 WL 644749, at \*16 (finding unsupported establishment claims to be false).

Despite advertising to consumers that Prevagen has been clinically shown to improve memory and provide other cognitive benefits, Defendants had no such evidence. Although the Madison Memory Study was an RCT, it was flawed, as discussed above, and does not substantiate the Challenged Establishment Claims.

**d. Challenged Health Efficacy Claims and Challenged Establishment Claims Were Material**

A claim is material if it “involves information important to consumers and, hence, [is] likely to affect their choice of, or conduct regarding a product.” *Med. Billers Network, Inc.*, 543 F. Supp. 2d at 304 (internal quotation marks omitted) (citing *FTC v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 529 (S.D.N.Y. 2000)); *see also Bronson Partners, LLC*, 564 F. Supp. 2d at 135-36 (finding a claim that the product causes weight loss to be material because the ad was almost entirely about weight loss). “Proof of actual consumer injury is not required.” *Bronson Partners, LLC*, 564 F. Supp. 2d at 135 (internal quotation marks omitted). Courts have found the following types of claims to be presumptively material: (1) express claims; (2) implied claims where there is evidence that the advertiser intended to make the claim; (3) claims that significantly involve health or safety; and (4) “claims pertaining to a central characteristic of the product about which reasonable consumers would be concerned.” *Fanning*, 821 F.3d at 172-73 (citing *Kraft, Inc.*, 970 F.2d at 322); *Med. Billers Network, Inc.*, 543 F. Supp. 2d at 304; *Bronson Partners, LLC*, 564 F. Supp. 2d at 135 (“The underlying rationale for finding a claim to be presumptively material ... is the assumption that the willingness of a business to promote its products reflects a belief that the consumers are interested in the advertising.” (internal quotation marks omitted)).

The Challenged Health Efficacy Claims and the Challenged Establishment Claims were clearly material. Not only were Defendants’ memory- and cognitive-improvement claims express or intended implied claims that Defendants communicated to consumers repeatedly through their advertisements, but such claims significantly involve health and pertain to a central characteristic of the product—improving a consumer’s memory and cognitive function. Therefore, the Challenged Health Efficacy Claims and the Challenged Establishment Claims must be presumed to be material under the law. *See, e.g., Wellness Support Network*, 2014 WL 644749, at \*17 (finding claims about preventing diabetes or reversing insulin resistance to involve a consumer’s health and thus presumptively material); *QT, Inc.*, 448 F. Supp. 2d at 965-66 (finding a claim that the product provided pain relief to be unquestionably health-related and therefore material); *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1191 (finding that “when a customer makes a decision to purchase a health product that he or she will ingest for purported health benefits, any claim on the label regarding the health benefits (i.e., any product efficacy claims) . . . can be presumed material”).

Because the Challenged Health Efficacy Claims and the Challenged Establishment Claims were likely to mislead consumers acting reasonably and are material, Defendants are liable for violating the FTC Act.

### **III. CORPORATE DEFENDANTS HAVE VIOLATED NEW YORK LAW**

New York Executive Law § 63(12) authorizes the NYAG to bring an action when a person or business engages in repeated or persistent fraudulent or illegal conduct. Fraud is defined as “any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions.” N.Y. Exec. Law § 63(12). It is not necessary to establish the traditional elements of common law fraud, such as intent to deceive and reliance, to establish liability for fraud under

Executive Law § 63(12). *People v. Trump Entrepreneur Initiative LLC*, 26 N.Y.S.3d 66, 72 (N.Y. App. Div. 2016); *see also People v. Apple Health & Sports Clubs, Ltd.*, 613 N.Y.S.2d 868, 869 (N.Y. App. Div. 1994). The test of fraudulent conduct under Executive Law § 63(12) is whether the act “has the capacity or tendency to deceive, or creates an atmosphere conducive to fraud.” *People v. Gen. Elec. Co.*, 756 N.Y.S.2d 520, 523 (N.Y. App. Div. 2003). Executive Law § 63(12) protects “not only the average consumer, but also ‘the ignorant, the unthinking and the credulous.’” *Id.* (quoting *Guggenheimer v. Ginzburg*, 43 N.Y.2d 268, 273 (N.Y. 1977)).

Both fraud and illegality must be repeated or persistent. “Repeated” is the “repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person.” N.Y. Exec. Law § 63(12). “Persistent” is the “continuance or carrying on of any fraudulent or illegal act of conduct.” *Id.* The NYAG is not required to establish that a large percentage of the person’s or business’s transactions were fraudulent or illegal. *State v. Princess Prestige*, 366 N.E.2d 61, 62 (N.Y. 1977); *People v. Credit Solutions of Am.*, No. 401225/09, 2012 N.Y. Misc. LEXIS 2090, at \*5 (N.Y. Sup. Ct. 2012).

New York General Business Law § 349(a) declares “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state” to be unlawful. General Business Law § 350 prohibits false advertising that is “misleading in a material respect.” Like Executive Law § 63(12), these statutes are construed broadly to effectuate their remedial purpose and apply to all “economic activity.” *See, e.g., Karlin v. IVF Am., Inc.*, 712 N.E.2d 662, 665 (N.Y. 1999). As with fraud under Executive Law § 63(12), the elements of common law fraud such as intent and reliance need not be established. *Koch v. Acker, Merrall & Condit Co.*, 967 N.E.2d 675, 676 (N.Y. 2012); *People v. Applied Card Sys., Inc.*, 805 N.Y.S.2d 175, 178 (N.Y. App. Div. 2005); *Gen. Elec. Co.*, 756 N.Y.S.2d at 523.

Representations are deceptive under GBL §§ 349 and 350 if they are “likely to mislead a reasonable consumer acting reasonably under the circumstances.” *Gaidon v. Guardian Life Ins. Co. of Am.*, 725 N.E.2d 598, 604 (N.Y. 1999); *Applied Card*, 805 N.Y.S.2d at 178. Repeated violations of GBL §§ 349 and 350 constitute illegal conduct under Executive Law § 63(12). *See, e.g., People v. Orbital Publ. Group, Inc.*, 95 N.Y.S.3d 28, 29-30 (N.Y. App. Div. 2019); *Applied Card*, 805 N.Y.S.2d at 177.

Case law under Section 5 of the FTC Act is given great weight in construing statutory fraud under Executive Law § 63(12) and deceptive practices and false advertising under the GBL. *See Applied Card Sys., Inc.*, 805 N.Y.S.2d at 178 (explicitly “recognizing that the interpretations of the Federal Trade Commission Act (*see* 15 U.S.C. § 45 *et seq.*) are useful in determining the aforementioned violations under both the Executive Law and General Business Law”); *State v. Feldman*, 210 F. Supp. 2d 294, 302 (S.D.N.Y. 2002); *Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank*, 647 N.E.2d 741, 744-45 (N.Y. 1995); *State v. Colorado State Christian Coll.*, 346 N.Y.S.2d 482, 487 (N.Y. Sup. Ct. 1973).

The parties do not dispute that Defendants’ advertisements at issue in this case were disseminated repeatedly in the State of New York, and they do not dispute that they sold hundreds of thousands of Prevagen products to addresses in the State of New York, including directly to consumers. (*See, e.g.,* Joint Pretrial Order (ECF No. 300) at 2 ¶ 11; Defs.’ 4th Supplemental Resps. & Objs. to Pls.’ 1st Set of Interrogatories (Oct. 23, 2022) at 10-11 & Ex. C, Joint Trial Exhibit JX-25.) It is therefore undisputed that, if Defendants’ advertisements at issue in this case are found to be deceptive, the NYAG prevails on its claims under Counts III and IV of the Complaint. The extent to which Defendants’ deceptive advertisements reached New York consumers, and to which Defendants sold Prevagen in New York, bears on the relief that the



NYAG seeks in this case. (*See infra* Section XIII.) Corporate Defendants’ fifteenth affirmative defense, that “[t]he alleged conduct complained of in the Complaint involves transactions or acts that took place outside of New York,” applies only to the scope of relief sought by the NYAG in this case.

For the foregoing reasons and the reasons stated in Section III above, Corporate Defendants have violated New York Executive and General Business Law. But, as Plaintiffs’ accompanying jury instructions reflect, the NYAG’s claims must be assessed under the language and application of these statutes, including the differing requirements of Executive Law § 63(12).

#### **IV. PLAINTIFFS HAVE APPLIED THE APPROPRIATE SUBSTANTIATION STANDARD AND FDA LAWS ARE INAPPLICABLE**

Contrary to Defendants’ arguments (Defs. Mot. for Summ. J. (ECF Nos. 220, 227)), Plaintiffs have applied the substantiation standard consistent with FTC law, parallel New York law, and FTC guidance, without violating Defendants’ due process rights, and FDA laws are inapplicable to this case. (*See* Pls. Opp’n to Defs. Mot. for Summ. J. (ECF No. 254) at 6-19.) Depending on the Court’s rulings, the issues raised in Plaintiffs’ opposition to Defendants’ motion for summary judgment could arise at trial.

#### **V. TESTIMONY OF DEFENDANTS’ EXPERTS SHOULD BE EXCLUDED**

Plaintiffs have moved to exclude expert testimony of Defendants’ experts, Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler, who offer inadmissible evidence: legal opinions, opinions based on unreliable methods or outside the scope of their expertise, testimony that is irrelevant to this case, and testimony that would only confuse the issues, mislead the jury, waste the Court’s time, or cause unfair prejudice. (*See* Pls. Mot. to Exclude (ECF No. 303) and Pls. Mem. in Supp. of Their Mot. to Exclude (ECF No.

304).) Depending on the Court’s rulings, the issues raised in Plaintiffs’ motion to exclude could arise at trial.

## **VI. CONSUMER TESTIMONIALS ARE NOT COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE**

At trial, Plaintiffs intend to show that Defendants’ advertisements, including advertisements that purportedly contain consumer testimonials, were false or unsubstantiated and were therefore deceptive. Consumer testimonials themselves are not competent and reliable scientific evidence and cannot substantiate efficacy claims for dietary supplements. *See Alcoholism Cure Corp.*, 2011 WL 13137951, at \*38 (granting FTC’s motion for summary judgment where defendant cited “no legal authority in support of his argument that anecdotal customer testimonials . . . may supplant competent and reliable scientific evidence to substantiate his health-related claims” concerning a dietary supplement); *FTC v. Ewing*, No. 14-CV-683, 2017 WL 4797516, at \*5 (D. Nev. Oct. 24, 2017) (“[A]necdotal evidence, such as testimonials by satisfied patients or statements by doctors that, based on their experience, they ‘believe’ a drug is effective,’ does not constitute competent and reliable scientific evidence.” (quoting *Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1143-44 (9th Cir. 1978))); *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1312 (noting that testimonials are not a form of proof).

## **VII. DEFENDANTS’ COLLINS QUALIFIER DOES NOT CURE THEIR DECEPTIVE ADVERTISING CLAIMS**

“Disclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression.” *Fleetcor Techs., Inc.*, 2022 WL 3273286, at \*9 (quoting *Removatron Int’l Corp.*, 884 F.2d at 1497) (finding as a matter of law that disclaimers, which used tiny, inscrutable print, did not cure a deceptive net impression). When disclaimers are insufficiently clear and conspicuous, they have no effect. “Anything less is only likely to

cause confusion by creating contradictory double meanings.” *Removatron Int’l Corp.*, 884 F.2d at 1497. Courts should focus on “the overall impression” created by the advertising without “emphasizing isolated words or phrases” such as disclaimers or qualifiers “apart from their context.” *Med. Billers Network, Inc.*, 543 F. Supp. 2d at 304; *see also Fleetcor Techs., Inc.*, 2022 WL 3273286, at \*9 (noting cases where the disclosures did not alter a deceptive net impression because they were too small, too vague, on the reverse side of materials, or contradicted the principal message of marketing materials); *FTC v. Minuteman Press*, 53 F. Supp. 2d 248, 262 (E.D.N.Y. 1998) (quoting *Removatron Int’l Corp.*, 884 F.2d at 1497) (rejecting argument that disclaimers in written materials cured the deceptive nature of conflicting oral representations); *Gaidon*, 725 N.E.2d at 604-605 (finding disclaimers inadequate to overcome deceptive practices claim under N.Y. GBL § 349); *Orbital*, 95 N.Y.S.3d at 30 (finding disclaimers inadequate to overcome claims under N.Y. Executive Law § 63(12) and GBL §§ 349 and 350).

Contrary to their argument, the Collins Qualifier does not shield Defendants from liability. Even if it cured the misleading claims, the Collins Qualifier was not used in advertising until approximately three years after the Complaint was filed, which means Defendants made the claims at issue for approximately thirteen years without such a Qualifier. Furthermore, the Collins Qualifier fails to alter the deceptive net impression of Defendants’ advertisements, and Defendants therefore continue to make the deceptive claims challenged in the Complaint.<sup>2</sup> (*See* Pls. Opp’n to Defs.’ Mot. for Summ. J. (ECF No. 254) at 30-36.) The Collins Qualifier is

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<sup>2</sup> Plaintiffs have also raised other issues regarding Defendants’ Collins Qualifier or the *Collins* settlement, including that Defendants have disseminated at least one advertisement post-settlement without the Collins Qualifier and that the *Collins* settlement does not cover all of claims at issue in this case. (*See* Pls. Opp’n to Defs. Mot. for Summ. J. (ECF No. 254) at 30-39.) The *Collins* settlement also does not apply to all of the Defendants in this case.

insufficiently prominent, appearing in small font on the back of packaging or briefly in a television commercial amidst other more prominent text or images that tout Prevagen's benefits. The Collins Qualifier also states that Defendants' claims are based on the results of subgroups of the Madison Memory Study, which were *post hoc*, flawed, and do not show any beneficial effect of Prevagen.

### **VIII. DECEPTIVE COMMERCIAL SPEECH ENJOYS NO CONSTITUTIONAL PROTECTION**

At trial, Plaintiffs will show that the Challenged Health Efficacy Claims and the Challenged Establishment Claims were deceptive and thus enjoy "no constitutional protection." *Quincy Bioscience Holding Co.*, 2020 WL 1031271, at \*3 (citing *Bristol Myers Co.*, 738 F.2d at 562). There can be "no constitutional objection" to the "suppression of commercial messages that do not accurately inform the public about lawful activity." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). As such, the government "may ban forms of communication more likely to deceive the public than to inform it." *Id.*; *see also Zauderer v. Off. of Disciplinary Couns. of the Sup. Ct. of Ohio*, 471 U.S. 626, 638 (1985) ("The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading[.]").

### **IX. EXISTENCE OF SATISFIED CUSTOMERS OR A LACK OF CONSUMER COMPLAINTS ARE NOT DEFENSES TO LIABILITY**

The existence of some satisfied customers does not constitute a defense to liability. *Five-Star Auto Club, Inc.*, 97 F. Supp. 2d at 530 (quoting *FTC v. Amy Travel Service, Inc.*, 875 F.2d 564, 572 (7th Cir. 1989)); *see also State v. Midland Equities of N.Y., Inc.*, 117 Misc. 2d 203, 207 (N.Y. Sup. Ct. 1982); *accord FTC v. Stefanchik*, 559 F.3d 924, 929 n.12 (9th Cir. 2009). As the Second Circuit wrote in affirming a Commission order in *Independent Directory Corp. v. FTC*,

[t]he fact that petitioners had satisfied customers was entire[ly] irrelevant. They cannot be excused for the deceptive practices here shown and found, and be insulated from action by the Commission in respect to them, by showing that others, even in large numbers, were satisfied with the treatment petitioners accorded them.

188 F.2d 468, 471 (2d Cir. 1951); *see also* *FTC v. Tashman*, 318 F.3d 1273, 1278 (11th Cir. 2003) (stating that the district court incorrectly focused on a few satisfied customers, rather than analyzing misrepresentations made about the product).

A lack of consumer complaints is also not a defense to liability under the FTC Act or parallel New York law. *FTC v. RagingBull.com, LLC*, 507 F. Supp. 3d 629, 634 (D. Md. 2020) (“[R]easonable consumers may be misled even where some consumers claim to be satisfied with a service or only a few consumers actually complained.”); *FTC v. Wilcox*, 926 F. Supp. 1091, 1099 (S.D. Fla. 1995) (rejecting argument that promotion was not deceptive because only a small percentage of consumers complained); *see also* *FTC v. Vocational Guides, Inc.*, No. 3:01-0170, 2006 WL 3254517, at \*14 (M.D. Tenn. Nov. 9, 2006) (evidence of few consumer complaints did not rebut evidence of misrepresentations); *State v. Mgmt. Transition Res., Inc.*, 115 Misc. 2d 489, 491 (N.Y. Sup. Ct. 1982) (noting “[i]t is not necessary for the Attorney-General to await consumer complaints before proceeding to enjoin” deceptive business practices).

Furthermore, the FTC is not required to show consumer injury. *See, e.g.,* *FTC v. Freecom Comms., Inc.*, 401 F.3d 1192, 1203 (10th Cir. 2005); *Braswell*, 2005 WL 4227194, at \*4. The NYAG is not required to show that any customer was injured. *See* *Goshen v. Mutual Life Ins. Co. of New York*, 98 N.Y.2d 314, 324 (N.Y. 2002). Rather, a misrepresentation is deceptive under the FTC Act and New York GBL §§ 349 and 350 if it is “likely to mislead consumers acting reasonably under the circumstances,” *see, e.g.,* *Five-Star Auto Club, Inc.*, 97 F. Supp. 2d at 526; *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994), or under New

York Executive Law § 63(12), if it has the capacity or tendency to deceive the credulous consumer, *see Gen. Elec. Co.*, 756 N.Y.S.2d at 523.

## **X. CORPORATE DEFENDANTS WERE A COMMON ENTERPRISE**

“Under the common enterprise theory, each entity within a set of interrelated companies may be held jointly and severally liable for the actions of other entities that are part of the group.” *FTC v. Tax Club, Inc.*, 994 F. Supp. 2d 461, 469-70 (S.D.N.Y. 2014) (noting that corporate entities that are part of the common enterprise “are liable for the conduct of other entities in the enterprise, regardless of whether the particular entity engaged in the behavior at issue”). “In determining whether a common enterprise exists among a set of corporate defendants, courts consider a set of non-dispositive factors, including whether they (1) maintain officers and employees in common, (2) operate under common control, (3) share offices, (4) commingle funds, and (5) share advertising and marketing.” *Id.* (internal quotation marks omitted); *see also New York v. Debt Resolve*, 387 F. Supp. 3d 358, 365-66 (S.D.N.Y. 2019). “[I]f the structure, organization, and operation of a business venture among separate corporate entities reveal a common enterprise or a ‘maze of interrelated companies,’” the FTC Act (and parallel New York law) disregard the corporate form. *FTC v. Consumer Health Bus. Ass’n*, No. 10-CIV-3551, 2012 WL 1890242, at \*5 (E.D.N.Y. May 23, 2012) (quoting *Del. Watch Co. v. FTC*, 332 F.2d 745, 746 (2d Cir. 1964)); *see Debt Resolve*, 387 F. Supp. 3d at 366. For example, courts have found entities to be a common enterprise when they are owned and managed by the same principles; pool resources, staff, and funds; and participated to some extent in the same common venture. *FTC v. Network Servs. Depot*, 617 F.3d 1127, 1143 (9th Cir. 2010); *Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d at 1182-84. Common enterprise is appropriate “in situations where corporations are so entwined that a judgment absolving one of them of liability would provide the other defendants with ‘a clear mechanism for avoiding the terms of the

order.’’ *Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d at 1182 (quoting *Del. Watch Co.*, 332 F.2d at 747).

The evidence shows that Corporate Defendants operated as a common enterprise. Corporate Defendants share a common business address and have been included together on consolidated financial and tax statements. Furthermore, they share the same corporate officers, including Mr. Underwood. Corporate Defendants’ business activities are also entwined around Prevagen. Quincy Bioscience Holding Company, Inc. wholly owns: Prevagen, Inc., which markets, oversees the manufacturing of, and sells Prevagen; Quincy Bioscience Manufacturing, LLC, which assists with the manufacturing of Prevagen; and Quincy Bioscience, LLC, the holder of Prevagen-related patents and trademarks.

#### **XI. MR. UNDERWOOD IS INDIVIDUALLY LIABLE**

Under FTC law,<sup>3</sup> an individual may be held liable for a corporation’s deceptive acts or practices if “with knowledge of the deceptive nature of the scheme, he either participate[s] directly in the practices or acts or ha[s] authority to control them.” *FTC v. Moses*, 913 F.3d at 306 (internal quotation marks omitted) (brackets in original); *FTC v. Quincy Bioscience Holding Co.*, 389 F. Supp. 3d 211, 220 (S.D.N.Y. 2019). Knowledge may be established by showing that an individual defendant “had actual knowledge of the deceptive conduct, [or] was recklessly indifferent to its deceptiveness, or had an awareness of a high probability of deceptiveness and intentionally avoided learning of the truth.” *Moses*, 913 F.3d at 307 (internal quotation marks omitted) (brackets in original). Intent to deceive does not need to be shown. *Five-Star Auto*

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<sup>3</sup> This Court previously dismissed the NYAG’s claims against Mr. Underwood on personal jurisdiction grounds. Opinion & Order (July 5, 2022) (ECF No. 272). At the conclusion of this matter, should Plaintiffs prevail against the Corporate Defendants, the NYAG intends to appeal this decision, seeking a ruling that this Court does, indeed, have personal jurisdiction over Mr. Underwood, and seeking a remand for further proceedings as appropriate. *See* Fed. R. App. P. 4(a)(1)(A).

*Club, Inc.*, 97 F. Supp. 2d at 535; *FTC v. Verity Int'l*, 335 F. Supp. 2d 479, 499 (S.D.N.Y. 2004) (“The FTC need not prove intent to defraud in order to establish a violation under the Act or to obtain injunctive . . . relief against an individual.”).

To find that an individual had the requisite authority to control, courts consider a variety of factors including whether the individual: formulated policies, oversaw and directed employees, signed corporate documents, controlled finances, created or reviewed the deceptive marketing materials, had active involvement in the business affairs, or otherwise held himself out as, or assumed the duties of, a corporate officer. *Moses*, 913 F.3d at 306-07; *Five-Star Auto Club, Inc.*, 97 F. Supp. 2d at 535-36; *Med. Billers Network, Inc.*, 543 F. Supp. 2d at 320-22; *Tax Club, Inc.*, 994 F. Supp. 2d at 471 (concluding that allegations that the individual served as the CEO of the corporate entities, was the sole owner, helped formulate policies on sales practices, and was authorized to operate bank accounts was sufficient to show control). Ultimate or sole control is not necessary to establish individual liability. *See, e.g., LeadClick Media*, 838 F.3d at 168 (stating that a deceptive scheme violating the FTC Act may have more than one perpetrator); *Direct Mkt'g Concepts, Inc.*, 624 F.3d at 12-13 (finding that defendant’s argument that there were gaps in his responsibilities, such as not editing the content of advertisements, was irrelevant because the evidence showed that defendant had the ability to cease the offending advertisements); *Fleetcor Techs., Inc.*, 2022 WL 3273286, at \*45 (finding sufficient evidence for control where the individual was in an “apex position and plainly paid close attention” to the company’s critical businesses and practices); *FTC v. World Media Brokers, Inc.*, No. 02C6985, 2004 WL 432475, at \*9 (N.D. Ill. Mar. 2, 2004) (holding an individual liable because she managed the telemarketing operation and the daily financial and administrative affairs, and arranged for credit card processing, despite not having sole control over the business).



The degree of participation in a corporation's business affairs is a relevant factor in determining whether an individual defendant had knowledge of the corporation's wrongful actions. *Moses*, 913 F.3d at 309 (noting that knowledge was supported by the individual defendant being aware of consumer complaints against the company by the Better Business Bureau and law enforcement agencies); *In re Sanctuary Belize Litig.*, 482 F. Supp. 3d 373, 398 (D. Md. 2020) (stating that an individual's "'pervasive role and authority' in an entity creates a 'strong inference' that the individual defendant had knowledge" (citing *FTC v. Commerce Planet, Inc.*, 878 F. Supp. 2d 1048, 1082 (C.D. Cal. 2012))); *Tax Club, Inc.*, 994 F. Supp. 2d at 472-73 (noting that an individual's participation in meetings to discuss complaints related to the practices at issue supported the conclusion that the individual had knowledge).

"Reliance on advice of counsel is not a valid defense on the question of knowledge required for individual liability." *FTC v. Cyberspace.com LLC*, 453 F.3d 1196, 1202 (9th Cir. 2006)) (brackets and internal quotation marks omitted). That is because the "blessing of an attorney" cannot make a deceptive statement truthful or "sanction something that the defendants should have known was wrong." *Amy Travel*, 875 F.2d at 575; *see also FTC v. Swatsworth*, No. 3:17-CV-340-GCM, 2018 WL 4016312, at \*6 (W.D.N.C. Aug. 22, 2018) (finding individual defendant liable under the FTC Act as a matter of law despite representations that the relevant documents had been reviewed by attorneys); *FTC v. Direct Benefits Grp., LLC*, No. 6:11-CV-1186-ORL-28TBS, 2012 WL 5508050, at \*3 (M.D. Fla. Nov. 14, 2012) (striking advice of counsel affirmative defense in ruling on admissibility of evidence for trial). Good faith is also not a defense to individual liability. *Quincy Bioscience Holding Co.*, 2020 WL 1031271, at \*3.

In this case, Mr. Underwood should be held *individually* liable. There is strong evidence showing that Mr. Underwood had extensive control over Corporate Defendants, including: being

the President and Chief Operating Officer of Corporate Defendants; a member of the Board of Directors and the largest individual shareholder of Quincy Bioscience; having direct oversight over Corporate Defendants' finance, research and development, and sales and marketing; being the final decision maker on advertising claims; and overseeing the development, conduct, and evaluation of the Madison Memory Study. Moreover, there is overwhelming evidence that Mr. Underwood participated in the practices at issue, including developing the idea to create Prevagen; appearing in Prevagen advertisements; creating or editing product labels and packaging, and TV and radio advertisements; being responsible for Corporate Defendants' regulatory compliance, including with the FDA; being an author of several Madison Memory Study papers; and participating in discussions about which subgroups of the Madison Memory Study to analyze. Additionally, Mr. Underwood also satisfies the knowledge requirement because of his involvement and oversight of the Madison Memory Study, participation in developing the advertising claims at issue, and his awareness of concerns about Prevagen's advertising claims.

## **XII. THE FTC IS ENTITLED TO A PERMANENT INJUNCTION WITH FENCING IN**

"The FTC Act provides that 'in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction.'" *FTC v. 1263523 Ontario Inc.*, 205 F. Supp. 2d 218, 221 (S.D.N.Y. 2002) (quoting 15 U.S.C. § 53(b)). "Violation of Section 5 of the FTC Act, 15 U.S.C. Section 45, constitutes a 'proper' case for the imposition of a permanent injunction." *Id.*; *see also FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. 1988). Misrepresentations of material facts made to induce the purchase of Prevagen constitute a deceptive act or practice and is prohibited by Section 5(a) of the FTC Act. *See*

*1263523 Ontario Inc.*, 205 F. Supp. 2d at 221. The FTC need not show that consumers relied on the claims at issue for injunctive relief. *Fleetcor Techs., Inc.*, 2022 WL 3273286, at \*22-23.

“It is settled that an action for an injunction does not become moot merely because the conduct complained of was terminated, if there is a possibility of recurrence, since otherwise the defendants ‘would be free to return to’ (their) old ways.”<sup>4</sup> *1263523 Ontario Inc.*, 205 F. Supp. 2d at 222 (entering permanent injunction even though the defendants were no longer engaging in the deceptive marketing scheme at issue); *FTC v. Bronson Partners, LLC*, 674 F. Supp. 2d 373, 393 (D. Conn. 2009) (stating that permanent injunctive relief would be appropriate when there is a cognizable danger of a recurrent violation and entering permanent injunction against defendants even though they were no longer selling the products at issue); *Fleetcor Techs., Inc.*, 2022 WL 3273286, at \*47 (stating that voluntary cessation of the conduct may not protect against future violations and that “[i]t is well-settled that permanent injunctive relief is appropriate if the defendant’s past conduct indicates that there is a reasonable likelihood of further violations in the future” (internal quotation marks omitted)).

Thus, “[i]f the FTC is able to demonstrate that there is ‘some cognizable danger of recurrent violation, something more than a mere possibility,’ then the FTC is entitled to injunctive relief.” *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1209 (quoting *United States v. W.T.*

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<sup>4</sup> *FTC v. Shire Viropharma*, 917 F.3d 147 (3d Cir. 2019), does not support Defendants’ argument that injunctive relief is precluded. *ViroPharma* sets forth a pleading standard. *Id.* at 161 (stating that “the FTC must plead that [the defendant] ‘is’ violating or ‘is about to’ violate the law”). That pleading standard has no relevance beyond the motion-to-dismiss stage. But in any event, it is satisfied where, as here, the challenged claims were ongoing at the time the complaint was filed. See *FTC v. Vyera Pharms., LLC*, No. 20-CV-706, 2020 WL 4891311, at \*43 (S.D.N.Y. Aug. 18, 2020) (denying motion to dismiss where complaint “adequately allege[d] that, as of the time it filed [the] lawsuit, the FTC had reason to believe that the defendants were at that very moment actively engaged in the” alleged violations); see also Pls. Opp’n to Defs. Mot. for Summ. J. (ECF No. 254) at 40-41.

*Grant Co.*, 345 US. 629, 633 (1953)). To determine whether a permanent injunction is appropriate, courts have considered factors such as: (1) whether the defendant had knowledge of the unlawful activities; (2) the nature or duration of the unlawful conduct; (3) whether the defendant is in a position to commit future violations; and (4) the harm to consumers if the conduct were to recur. *See, e.g., FTC v. Micom Corp.*, No. 96-0472, 1997 WL 226232, at \*2 (S.D.N.Y. Mar. 12, 1997) (finding that a permanent injunction was warranted because the defendants had knowledge of the unlawful practices and the practices were not isolated); *Fleetcor Techs., Inc.*, 2022 WL 3273286, at \*48-49; *FTC v. SuperTherm Inc.*, No. CV-20-08190, 2021 WL 3419035, at \*7 (D. Ariz. Aug. 5, 2021) (finding an injunction to be appropriate where the misrepresentations were ongoing over a six-year period and the individual defendants continued to own companies engaged in a similar business); *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1209. For example, the *Fleetcor* court found a permanent injunction to be appropriate where the deceptive advertising practices were “ingrained in the fabric of the company for years,” the defendants continued to be fully operational, there were opportunities for future violations, and the defendants did not recognize the wrongful nature of their conduct. 2022 WL 3273286, at \*48-49.

With regard to the scope of injunctive relief, a permanent injunction must bear a “reasonable relation to the unlawful practices found to exist.” *FTC v. Grant Connect, LLC*, 763 F.3d 1094, 1105 (9th Cir. 2014) (quoting *FTC v. Colgate-Palmolive*, 380 U.S. 374 (1965)). In determining the scope of a permanent injunction, courts consider: “(1) the seriousness and deliberateness of the violation; (2) [the] ease with which the violative claim may be transferred to other products; and (3) whether the [defendant] has a history of prior violations.” *Grant Connect, LLC*, 763 F.3d at 1105. The FTC “is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past.” *Id.* (quoting *FTC v. Ruberoid*

*Co.*, 343 U.S. 470, 473 (1952)). “Although injunctive relief should be tailored to address specific harms and not impose unnecessary burdens on lawful activity, courts may enjoin otherwise legitimate conduct in order to prevent future violations.” *Verity Int’l*, 335 F. Supp. 2d at 499; *see also Bristol-Myers*, 738 F.2d at 561 (finding that fencing-in relief was appropriate where the defendant spent over two hundred fifty million dollars in advertising and made ten deceptive claims); *ITT Cont’l Baking Co. v. FTC*, 532 F.2d 207, 223 (2d Cir. 1976) (noting that courts have affirmed FTC orders “encompassing all products or all products in a broad category, based on violations involving only a single product or group of products”); *FTC v. Pukke*, No. 20-2215, 2022 WL 16568278, at \*12 (4th Cir. Nov. 1, 2022) (stating that defendants who violate the FTC Act must expect some fencing in and that the injunctions can be framed broadly enough to prevent similar illegal practices in future advertisements). “The reasonable relationship analysis operates on a sliding scale[—]any one factor’s importance varies depending on the extent to which the others are found. In other words, the more serious a violation, the less important transferability and prior history become.” *Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006).

In their motion for summary judgment, Defendants contend that Plaintiffs are not entitled to injunctive relief. (Defs. Mot. for Summ. J. (ECF Nos. 220, 227).) However, these arguments are without merit, and for the reasons stated in Plaintiffs’ opposition to that motion, the Court can—and should—order permanent injunctive relief with fencing in. (*See* Pls. Opp’n to Defs. Mot. for Summ. J. (ECF No. 254) at 37-46.). Permanent injunctive relief is appropriate here because there is a cognizable danger of recurring violation: Defendants had knowledge of Prevagen’s deceptive claims, which were disseminated to consumers for approximately fifteen years through national advertising; Mr. Underwood continues to own and control Corporate

Defendants as well as participate in the challenged conduct; and Defendants continue to sell Prevagen using the same deceptive claims, even with the Collins Qualifier. Furthermore, fencing in relief would be warranted because Defendants deliberately made false or unsubstantiated claims for fifteen years, the claims were express and involved consumers' health, and violative claims involve ingredients, like apoaequorin or Vitamin D, that can be transferred easily to other products.

### **XIII. THE NYAG IS ENTITLED TO A PERMANENT INJUNCTION, PENALTIES, DISGORGEMENT, RESTITUTION, AND COSTS**

#### **a. The NYAG Is Entitled to an Injunction**

For the reasons stated in Section XII above, the NYAG is also entitled to injunctive relief. Additionally, under the New York laws at issue, the NYAG need not establish that the conduct is likely to recur in order to obtain injunctive relief. *See, e.g., People v. Applied Card Sys., Inc.*, 11 N.Y.3d 105, 109 (2008); *People v. Gen. Elec. Co.*, 756 N.Y.S.2d 520, 524 (N.Y. App. Div. 2003) (“Even though GE voluntarily ceased its deceptive practices, the IAS court . . . retained the power to grant injunctive relief . . .” (citations omitted)). In *State v. Midland Equities*, 117 Misc. 2d 203, 206-07 (N.Y. Sup. Ct. 1982), the court recognized that “[v]oluntary discontinuance of improper or illegal activity is no assurance that such activity will not be resumed” and that “even if the court were to credit respondents’ representations with regard to future activity, an order granting injunctive relief would not harm respondents and could be properly granted.” *See also People v. Ludwig Baumann & Co.*, 56 Misc. 2d 153, 160 (N.Y. Sup. Ct. 1968) (finding that the injunction will serve as a deterrent to the respondents and any others who may be inclined to “prey upon a gullible and unwary public”).

**b. The NYAG Is Entitled to Statutory Penalties**

The NYAG intends to seek penalties in an amount sufficient to send a message to Corporate Defendants that their continued deception of New York consumers will not be tolerated, and to send a message to other would-be deceptive advertisers that fraudulent claims will not be tolerated. New York General Business Law § 350-d authorizes the Court to award civil penalties in an amount up to \$5,000 for each violation of New York General Business Law §§ 349 and 350. Plaintiffs’ proposed jury instructions outline the standards and criteria applicable to determining a penalty amount, as discussed below.

The purpose of statutory penalties is to “punish unlawful conduct and to deter future violations.” *People v. Applied Card Sys., Inc.*, No. 2073-03, 2006 N.Y. Misc. LEXIS 9527, at \*23 (N.Y. Sup. Ct. Jan. 19, 2006). In assessing civil penalties, courts have rejected the application of a rigid, mathematical formula and instead have articulated broad and flexible standards and principles. “[C]onsideration may be given to such factors as the injury to the public, the good or bad faith of the defendant, the defendant’s ability to pay, whether the amount of the penalty would be a meaningful deterrent from engaging in such unlawful conduct in the future, and whether the penalty would eliminate the benefit derived by the violations or shock one’s sense of fairness.” *Id.* at 24. Among the most important factors are the length and extent of the wrongdoing and the number of consumers affected. Thus, in *People v. Orbital Publ. Group*, 193 A.D.3d 661, 662 (N.Y. App. Div. 2021), New York’s Appellate Division affirmed a penalty of \$7,406,900, finding such a penalty proportionate to a years-long deceptive scheme that affected “tens of thousands of New Yorkers” even though the appellant claimed to have earned only \$20,000 a year. *See Br. for Resp.-Appellant, New York v. Orbital Publ. Group*, No. 2020-03013, 2020 N.Y. App. Div. Briefs LEXIS 4572, at \*5 (N.Y. App. Div. Oct. 12, 2020).

The total amount of the penalty imposed should not be so small as to represent merely a cost of doing business, and should be large enough to serve as a warning and to discourage the prohibited act, both as to the defendants and other would-be violators of the law. *See Meyers Bros. Parking Sys. v. Sherman*, 87 A.D.2d 562, 563 (N.Y. App. Div. 1982), *aff'd*, 57 N.Y.2d 653 (1982) (“If the penalties were limited to \$350 maximum on a single day, the fine would simply be a cost of doing business . . . [and] would hardly satisfy the legislative purpose or act as a warning to discourage the prohibited act.”). Where, as here, the deceptive acts are deliberate and egregious (*see supra* Sections III & IV), the maximum penalty can be warranted. *See People v. McNair*, 9 Misc. 3d 1121[A], 2005 N.Y. Slip Op. 51727[U], at 3 (N.Y. Sup. Ct. 2005).

Here, the NYAG is entitled to statutory penalties from October 6, 2013, to present. This is based on the three-year statute of limitations for claims under GBL §§ 349 and 350 in effect at the time this action was filed in 2017, *see Gaidon v. Guardian Life Ins. Co. of Am., Inc.*, 96 N.Y.2d 201, 210 (N.Y. 2001), plus an additional 95 days due to a tolling agreement entered into between the parties during the course of the NYAG’s pre-suit investigation. Because the Complaint was filed on January 9, 2017, the reach of the NYAG’s claims for penalties dates back to 95 days prior to January 9, 2014—October 6, 2013.

The number of violations can be measured in a number of ways. The jury can consider, for example, the number of advertisements in New York or the number of sales made in New York. Regardless of the calculation methodology, the jury can take into account the ubiquity of Defendants’ advertising in determining the amount of penalty to assess for each violation. *Cf. Applied Card*, 2006 N.Y. Misc. LEXIS 9527, at \*42 (finding maximum penalties justified for a “particularly abhorrent practice”).



Here, penalties can be based on Defendants’ widespread advertising campaign for Prevagen. Deceptive television advertisements ran nationally on multiple television programs for the entire relevant period. Defendants’ advertisements appeared on dozens of television stations and national television programs from June 2015 to October 2020. (*See* Joint Pretrial Order (ECF No. 300) Ex. A.) The NYAG expects that, when Defendants update the relevant interrogatory response, the response will show that deceptive advertisements continued to air from October 2020 through the present day.

Additionally, Defendants aired a deceptive infomercial on 19 different New York television stations for six months during the relevant time period—from October 2013 to June 2014—and another deceptive infomercial on 37 different New York television stations from April 2014 to April 2015. (*See id.*) And Defendants also aired 11 different advertisements on multiple national radio programs for multiple years during the relevant time period. (*See id.*)

Defendants’ advertising is not limited to television and radio. Every Prevagen label makes unsubstantiated advertising claims, and Defendants offered Prevagen with deceptive labels for sale every day during the relevant time period. Moreover, Defendants’ website, with its own deceptive advertising claims, has been available for New York consumers to access every day during the relevant time period.

Penalties can also be assessed based on the number of sales of Prevagen products to New York consumers. Given the ease of determining the number of sales in New York, this would be an appropriate and straightforward method of calculating Defendants’ violations. *See People v. Image Plastic Surgery, LLC*, No. 450389/19, 2022 N.Y. App. Div. LEXIS 6082, at \*3 (N.Y. App. Div. Nov. 3, 2022) (determining that penalty is “properly connected to the number of consumers affected by the advertising”); Judgment, *People v. Credit Solutions of Am., Inc.*, No.

401225/09 (N.Y. Sup. Ct. Dec. 14, 2012) (imposing \$100 penalty for each of 20,588 customers deceived); *Applied Card*, 2006 N.Y. Misc. LEXIS 9527, at \*30 (penalty for each violation may be assessed for “each improper consumer transaction”).

Basing the number of violations on the number of sales in New York is reasonable in light of the fact that, but for the promises of improved memory and providing other cognitive benefits—promises that are made on every single Prevagen product label—there is no reason for consumers to purchase the product. *Image Plastic Surgery*, 2022 N.Y. App. Div. LEXIS 6082, at \*2 (accepting the substance of defendants’ misrepresentations as evidence of materiality). Defendants are expected to update their interrogatory response indicating the number of Prevagen products sold in the State of New York during the relevant time period. To date, Defendants have provided the data for 2014 to August 2020, and that data indicates that more than [REDACTED] Prevagen products were sold and shipped to New York addresses. (*See* Defs.’ 4th Supplemental Resps. & Objs. to Pls.’ 1st Set of Interrogatories (Oct. 23, 2022) Ex. C, Joint Trial Exhibit JX-25.) If the jury were to impose the maximum penalty of \$5,000 per sale, the penalty would be more than [REDACTED]. While the NYAG is not recommending a penalty of that amount at this time, the precise figure that is appropriate will depend on Defendants’ updated discovery responses and production of documentation regarding their financials.

Any ultimate penalty here should also take into consideration the size and financial state of the Defendant corporations, including the amount of money spent on advertising. In this case, Defendants have reaped profits of more than [REDACTED] during the relevant time period, and they have used those profits to continue to make their deceptive advertising claims. (*See* Defs.’ 4th Supplemental Resps. & Objs. to Pls.’ 1st Set of Interrogatories (Oct. 23, 2022) at 10 & Ex. B, Joint Trial Exhibit JX-25.) *United States v. J.B. Williams*, 354 F. Supp. 521, 549 (S.D.N.Y.

1973) (in determining penalties, concluding that the “actual financial condition” of the defendant was reflected by its “considerable business operations,” including advertising expenditures in excess of \$10 million per year). The NYAG expects to present updated figures to the jury once Defendants have provided them and to propose an appropriate penalty amount based in part on that data.

**c. The NYAG Is Entitled to Restitution, Disgorgement, and Costs**

Should the NYAG prevail on its claims at trial, the NYAG would be entitled to seek the equitable relief requested in the Complaint, as well as statutory costs. Because the NYAG’s Executive Law § 63(12) claims are subject to a six-year statute of limitations (*see* N.Y. C.P.L.R. 13(9)), the remedies of disgorgement and restitution cover a time period of six years prior to the filing of the Complaint in this matter, plus an additional 95 days due to a tolling agreement entered into between the parties during the course of the NYAG’s pre-suit investigation. Because the Complaint was filed on January 9, 2017, the reach of the NYAG’s disgorgement and restitution claims therefore dates to October 6, 2010 (95 days prior to January 9, 2011).

Restitution under Executive Law § 63(12) is a “vehicle by which aggrieved consumers [can] recover the money which is due them without resorting to costly litigation.” *State v. Ford Motor Co., Inc.*, 136 A.D.2d 154, 158 (N.Y App. Div. 1988). As with other relief authorized under § 63(12), restitution is appropriate even in the absence of bad faith. *Id.* Because Defendants deceptively advertised that Prevagen could improve memory and provide other cognitive benefits, consumers who purchased those products are entitled to full refunds.

Restitution is available for the time period from October 6, 2010 through the present. However, because of the class action settlement in *Collins v. Quincy Bioscience, LLC*, the NYAG is not seeking restitution on behalf of individuals in the settlement class, which was defined as individuals who purchased Prevagen from January 1, 2007 through July 21, 2020,

who did not opt out of the settlement class. (*See Collins* Final Order & Judgment (Nov. 18, 2020) at 4 (defining settlement class); *Collins* Order Granting Pls’ Am. Unopposed Mot. for Preliminary Approval of Class Action Settlement & Certification of the Settlement Class (July 21, 2020).) The NYAG is therefore seeking restitution for all New York consumers who purchased Prevagen from July 21, 2020 to the present date.

The NYAG is entitled to seek an accounting in order to facilitate restitution. *See, e.g., People v. Quality King Distribs., Inc.*, 173 N.Y.S.3d 221 (N.Y. App. Div. 2022); *People v. Telehublink Corp.*, 301 A.D.2d 1006, 1007-10 (N.Y. App. Div. 2003); *People v. Lipsitz*, 174 Misc. 2d 571, 583 (N.Y. Sup. Ct. 1997). However, in order to determine the appropriate amount, the NYAG intends to rely on Defendants’ updated response to Interrogatory No. 1, which details the revenue received from sales of Prevagen to New York addresses, including both sales to third-party retailers and direct-to-consumer sales.

The NYAG is also entitled to seek disgorgement under Executive Law § 63(12). *See People v. Greenberg*, 27 N.Y.3d 490, 497-98 (2016). In this case, the NYAG seeks to deprive Defendants of their ill-gotten gains from the sales of Prevagen in New York. “Disgorgement . . . focuses on the gain to the wrongdoer” and thus “aims to deter wrongdoing by preventing the wrongdoer from retaining ill-gotten gains from fraudulent conduct.” *People v. Ernst & Young LLP*, 114 A.D.3d 569, 569 (N.Y. App. Div. 2014). “Accordingly, the remedy of disgorgement does not require a showing or allegation of direct losses to consumers or the public; the source of the ill-gotten gains is ‘immaterial.’” *Id.*

“Maintaining disgorgement as a remedy within the court’s equitable powers is crucial, particularly where the Attorney General may be precluded from seeking restitution and damages if defendant settled the private class action against it.” *Ernst & Young LLP*, 114 A.D.3d at 570;

*cf. People v. Greenberg*, No. 401720/05, 2014 N.Y. Misc. LEXIS 2377, at \*5 (N.Y. Sup. Ct. May 28, 2014) (disgorgement also available under the Martin Act as an “equitable remedy”). To the extent that the jury awards statutory penalties to the NYAG, the Court may take that amount into account when determining the appropriate amount for disgorgement. The Court may, for example, award disgorgement for the period October 6, 2010 to October 5, 2013, the period for which the NYAG is not seeking a statutory penalty. (*See supra* Section XIII.b.)

Finally, the NYAG is entitled to seek statutory costs pursuant to New York Civil Practice Law & Rules § 8303(a)(6) in the amount of \$2,000 against each Corporate Defendant, for a total sum of \$8,000.

**d. Outstanding Discovery Responses Relating to Advertising and Finances**

Because Defendants continue to disseminate their deceptive advertisements and continue to sell Prevagen throughout the United States, including in New York, Plaintiffs intend, at the appropriate time, to seek updated discovery responses from them with respect to such advertisements and such sales. In accordance with Rule 26(e)(1)(A) of the Federal Rules of Civil Procedure, Defendants are obligated to supplement their interrogatory responses if they are incomplete. *See Arthur v. Atkinson Freight Lines Corp.*, 164 F.R.D. 19, 20 (S.D.N.Y. 1995) (recognizing affirmative duty to supplement disclosure). Specifically, Plaintiffs intend to seek updated responses to Interrogatory Nos. 1, 3, 4, 5, 6, 8, and 20, as well as an updated production of audited financial statements in partial response to Interrogatory No. 20. Should Defendants refuse to provide this updated discovery—most of which they previously agreed to provide—Plaintiffs intend to petition this Court to compel Defendants to provide updated responses.

Interrogatory Nos. 1, 6, and 20 relate to the sales of Prevagen in the United States and in New York; the revenues and gross and net profits related to those sales; the finances of the Corporate Defendants; and the amount of expenditures Defendants made on marketing and

advertising Prevagen products. This data is directly relevant, at a minimum, to the monetary relief sought by the NYAG. (*See supra* Sections XIII.b & XIII.c.)

Interrogatory Nos. 3-5 and 8 relate to the dissemination of Defendants' deceptive advertisements. Specifically, they relate to the dissemination of the claims at issue in this case via television advertisements and infomercials (Interrogatory No. 3); radio advertisements (Interrogatory No. 4); promotional books and pamphlets (Interrogatory No. 5); and product packaging and labeling (Interrogatory No. 8). The extent to which Defendants have disseminated their deceptive claims, both across the United States and in New York, is relevant to the injunctive relief sought by both Plaintiffs as well as the monetary relief sought by the NYAG. (*See supra* Sections XII & XIII.)

#### **XIV. EXHIBIT LIST EVIDENTIARY ISSUES**

Defendants have made multiple meritless objections to several of Plaintiffs' proposed trial exhibits, while listing numerous inadmissible documents among their own proposed exhibits. Plaintiffs herein will not address all of Defendants' problematic objections, nor will they discuss all possible objections to Defendants' documents.<sup>5</sup> Rather, Plaintiffs will highlight for the Court those objections where Defendants' arguments most clearly lack merit.

##### **a. Defendants' Objections to Plaintiffs' Proposed Exhibits**

Defendants have objected on hearsay grounds to many of their own documents, including their Answers to Plaintiffs' Complaint, responses to the FTC's civil investigative demand, and emails of company employees. In so doing, Defendants ignore clear case law providing that such documents and statements therein constitute judicial admissions of fact by which they are

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<sup>5</sup> Plaintiffs, for example, for the most part will not address objections on the basis of relevance, prejudicial effect, cumulativeness, or foundation, as they believe such objections are more appropriately addressed on a document-by-document basis at trial.

bound or are not hearsay as statements of a party opponent under Federal Rule of Evidence 801(d)(2). Defendants also have made hearsay objections to documents relating to data and their statistical analyses of data from their own studies. As an initial matter, such data and analyses would not be hearsay to the extent Plaintiffs did not offer them to prove the truth of the matters asserted. Furthermore, such data and analyses would not be hearsay under the Federal Rules of Evidence. To the extent the data were generated automatically by machines, they would not constitute statements made by a person (declarant), as required under Fed. R. Evid. 801(a)-(c). Additionally, where Defendants have used underlying data to perform analyses and draw inferences, the data would constitute “adopted” statements of a party opponent under Fed. R. Evid. 801(d)(2)(B). Analyses of study data performed by Defendants’ employees or agents would be statements of a party opponent under Fed. R. Evid. 801(d)(2)(D).

Defendants also have objected on authentication grounds to certain advertisements that Plaintiffs have captured because Defendants have failed to produce them, despite Plaintiffs’ numerous requests. Defendants’ authentication objections to Plaintiffs’ captures of their own advertisements would only serve to waste trial time on unnecessary foundation testimony.

**i. Defendants’ Meritless Hearsay Objections to Their Own Documents**

Defendants’ hearsay objections to their own Answers in this matter are utterly baseless. *See* Pls.’ Exs. PX-21—22. Second Circuit case law provides that “[a] party’s assertion of fact in a pleading is a judicial admission by which it normally is bound throughout the course of the proceeding.” *Bellefonte Re Ins. Co. v. Argonaut Inc. Co.*, 757 F.2d 523, 528 (2d Cir. 1985); *see also Western World Ins. Co. v. Stack Oil, Inc.*, 922 F.2d 118, 121 (2d Cir. 1990) (party’s factual concession in its answer and counterclaim was a judicial admission that was conclusive against party); *Marathon Enters., Inc. v. Schröter GMBH & Co.*, No. 01 Civ. 0595(DC), 2003 WL 355238, at \*4 (S.D.N.Y. Feb. 18, 2003) (“Courts have specifically found that admissions in a

party's answer constitute judicial admissions to which the party is subsequently bound.") (listing cases). Judicial admissions "*may not be controverted at trial or on appeal*. Indeed, they are not evidence at all but rather have the effect of withdrawing a fact from contention." *Guadagno v. Wallack Ader Levithan Assocs.*, 950 F. Supp. 1258, 1261 (S.D.N.Y. 1997) (quoting *Keller v. United States*, 58 F.3d 1194, 1199 n.8 (7th Cir. 1995)) (internal quotations omitted) (emphasis added); *see also Banks v. Yokemick*, 214 F. Supp. 2d 401, 405 (S.D.N.Y. 2002) (judicial admissions "obviate the need for debate, discussion or discovery regarding particular factual issues" and "remove [those issues] from dispute"). Therefore, factual assertions in Defendants' Answers are conclusive, and Defendants may not dispute them on hearsay or other evidentiary grounds. *See Guadagno*, 950 F. Supp. at 1261; *Shearon v. Womack*, No. 3:15-cv-01061, 2017 WL 6381432, at \*2 (M.D. Tenn. Dec. 14, 2017) (overruling hearsay objections, finding that "[a]s judicial admissions are not evidence, there is no reason why they should be subject to the Rules of Evidence, such as hearsay").<sup>6</sup>

Defendants also have objected on hearsay grounds to their answers to interrogatories contained in the FTC's Civil Investigative Demand, a form of compulsory process the FTC served on them prior to initiating the instant lawsuit. *See* FTC Act, 15 U.S.C. § 57b-1 (civil investigative demands); Pls.' Exs. PX-8—9. Notably, Defendants do not object on hearsay grounds to their answers to Plaintiffs' post-Complaint interrogatories. Defendants thus apparently concede, correctly, that such answers qualify as statements of a party opponent when

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<sup>6</sup> Furthermore, even if factual statements in Defendants' Answers were not judicial admissions, they would be statements of a party opponent, and therefore not hearsay, under Fed. R. Evid. 801(d)(2). *See* Fed. R. Evid. 801(d)(2); *Liu v. Little Saigon Cuisine Inc.*, 18-CV-2181 (RPK) (VMS), 2021 WL 4487839, at \*3 (E.D.N.Y. Sept. 30, 2021) (overruling hearsay objection to admission of complaint, finding that factual statements in complaint were judicial admissions and complaint constituted the statement of a party opponent under Fed. R. Evid. 801(d)(2)).



offered against them. Defendants therefore seem to draw a distinction between their pre-Complaint and post-Complaint interrogatory answers. There is no basis for such a distinction, however, as Federal Rule of Evidence 801(d)(2) does not limit the scope of party statements to those made following the initiation of a lawsuit. *See* Fed. R. Evid. 801(d)(2). In the course of conferring on the parties' proposed trial exhibits, Defendants offered no rationale for distinguishing between pre- and post-Complaint interrogatory responses with regard to party statements, and, not surprisingly, have proffered no case law in support of their position. Defendants' responses to the CID interrogatories, which Defendants have not challenged on authenticity grounds, are unquestionably their own written statements. They thus qualify as statements of a party opponent and are not hearsay.

Defendants additionally have objected on hearsay grounds to emails of their own employees and agents. *See, e.g.*, Pls.' Exs. PX-148, 163, 188. Emails of a party's employees or agents acting within the scope of their employment or agency, however, are statements of a party opponent under Federal Rule of Evidence 801(d)(2)(D), and therefore are not hearsay. *See New World Trading Co. v. 2 Feet Prods., Inc.*, Nos. 11 Civ. 6219(SAS), 13 Civ. 1251(SAS), 2014 WL 988475, at \*1 (S.D.N.Y. March 13, 2014); *see also Columbia Cas. Co. v. Neighborhood Risk Mgmt. Co.*, No. 14-cv-48(AJN), 2016 WL 4467548, at \*2, \*5 & n.1 (S.D.N.Y. Aug. 22, 2016) (email of company's consultant was statement of a party opponent under Fed. R. Evid. 801(d)(2)(D)).<sup>7</sup>

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<sup>7</sup> An employee need not have any minimum seniority for his or her statements to qualify as statements of a party opponent under Fed. R. Evid. 801(d)(2)(D). *See FTC v. Vyera Pharms. LLC*, No. 20cv00706 (DLC), 2021 WL 5236333, at \*3 (S.D.N.Y. Nov. 10, 2021) (noting that Rule 801(d)(2)(D) has no limitation based on seniority or status of an employee, but "[i]nstead, it is limited by the relationship between the statements to the employee's duties and the scope of those duties"). Additionally, statements of employees that meet the requirements of Fed. R. Evid. 801(d)(2)(D) are admissible against corporate officers. *See id.*

Defendants also have objected on hearsay grounds to data, and analyses of data, from their own studies. *See, e.g.*, Pls.’ Exs. PX-163—167. Such objections are without merit. As an initial matter, such data or analyses would not be hearsay to the extent Plaintiffs offered them for a purpose other than proving the truth of the matters asserted. *See* Fed. R. Evid. 801(c) (defining hearsay as a statement offered to prove the truth of the matter asserted in the statement).

Plaintiffs, for example, could offer such documents not to prove the results of the analyses, but rather to show the number and scope of the analyses Defendants performed. Furthermore, such data and analyses are not hearsay under the Federal Rules of Evidence. To the extent the data were generated automatically by machines, they would not constitute statements made by a person (declarant), as required under Fed. R. Evid. 801(a)-(c). *See United States v. Channon*, 881 F.3d 806, 811 (10th Cir. 2018); *United States v. Khorozian*, 333 F.3d 498, 506 (3d Cir. 2003). Additionally, where Defendants have used underlying data to perform analyses and draw inferences, they have manifested a belief in the data’s accuracy, and the data would constitute an “adopted” statement of a party opponent under Fed. R. Evid. 801(d)(2)(B). *See Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 239 (2d Cir. 1999) (survey commissioned by party opponent was admissible as an adopted statement under Rule 802(d)(2)(B), where opponent, by analyzing and drawing inferences from survey, had manifested a belief in survey’s trustworthiness); *Lear Auto. Dearborn, Inc. v. Johnson Controls, Inc.*, 789 F. Supp. 2d 777, 780-86 (E.D. Mich. 2011) (survey data was admissible under Rule 801(d)(2)(B) where party opponent had manifested a belief in data’s truth by supplying them to its expert, who used them in formulating his opinions); *see also Wynn v. City of Indianapolis*, No. 1:20-cv-1638-JMS-MJD, 2022 WL 1120490, at \*15-16 (S.D. Ind. Apr. 14, 2022) (spreadsheets of data published by party on its website were admissible under Rule 801(d)(2), as they were party statements and party had

manifested on the website an adoption or belief that the data were true). Furthermore, *analyses* of data performed by Defendants' employees or agents would constitute statements of an opposing party under Fed. R. Evid. 801(d)(2)(D). *See Schering Corp.*, 189 F.3d at 238-39 (party's analysis of survey was a party admission under Rule 801(d)(2)(D)).

**ii. Defendants' Authentication Objections Would Only Serve to Waste Trial Time**

Defendants have objected on authentication grounds to multiple advertisements captured by Plaintiffs. *See, e.g.*, Pls.' Exs. PX-543, 545, 548, 550. Plaintiffs, however, have listed such advertisements because Defendants have failed to produce copies of them as required under the Federal Rules. As detailed in Plaintiffs' opposition to Defendants' summary judgment motion, Plaintiffs repeatedly have asked Defendants to update their discovery responses by producing advertisements and dissemination information. *See* Pls. Opp'n to Defs' Mot. for Summ. J. (ECF No. 254) at 32 n.10.<sup>8</sup> Defendants' refusal to stipulate to the authenticity of Plaintiffs' captures of their own advertisements would only serve to waste trial time on unnecessary foundation testimony.

**b. Defendants' Inadmissible Documents**

Defendants have listed numerous inadmissible documents among their proposed trial exhibits, including their own expert witnesses' written reports, various scientific articles, their own written responses to Plaintiffs' discovery requests, documents relating to the prescription drug Aduhelm and the FDA, and documents from the class-action lawsuit settled by Defendants. As set forth below, these documents are inadmissible.

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<sup>8</sup> Additionally, following the parties' conferral regarding proposed trial exhibits, Plaintiffs sent Defendants a letter asking them to either produce the advertisements in question or withdraw their authentication objections. Defendants have failed to do either.

Written reports of expert witnesses constitute inadmissible hearsay. *See Ake v. General Motors Corp.*, 942 F. Supp. 869, 877-78 (E.D.N.Y. 1996) (expert's report was hearsay, noting that report was not admissible as a basis for expert's opinion because the report *was* the expert's opinion); *Granite Partners, L.P. v. Merrill Lynch*, No. 96 CIV 7874 (RWS), 2002 WL 826956, at \*7 (S.D.N.Y. May 1, 2002).<sup>9</sup> Scientific articles also are inadmissible hearsay. *See Glowczenski v. Taser Int'l, Inc.*, 928 F. Supp. 2d 564, 572 (E.D.N.Y. 2013).<sup>10</sup> While certain statements in such articles may be admissible under the "learned treatise" exception to the rule against hearsay, a party seeking admission of such statements must (1) call them to the attention of a testifying expert witness and (2) establish the publication as a reliable authority. Fed. R. Evid. 803(18); *Glowczenski*, 928 F. Supp. 2d at 572. Furthermore, even if a party satisfies those requirements, the statement may only be read into evidence; neither the statement nor the article may be received as an exhibit. *See* Fed. R. Evid. 803(18).

Defendants' written responses to Plaintiffs' discovery responses constitute inadmissible hearsay, as well. *See Int'l Bus. Machs. Corp. v. BGC Partners*, No. 10-cv-128, 2013 WL 1775367, at \*25-26, n.8 (S.D.N.Y. Apr. 25, 2013) ("If a party relies upon an opposing party's answers to interrogatories, the answers are admissible statements of a party opponent, but a party's own answers to interrogatories are not so admissible.") (citation omitted); *Gilmore v. Macy's Retail Holdings*, No. CIV 06-3020-JBS, 2009 WL 140518, at \*9 (D.N.J. Jan. 20, 2009) (a party "may not introduce statements from its own answers to interrogatories or requests for

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<sup>9</sup> *See* Defs.' Exs. DX-443—47 (Defendants' expert reports).

<sup>10</sup> *See* Defs.' Exs. DX-2—77 (examples of scientific articles).

admission as evidence because such answers typically constitute hearsay when used in this manner”) (quoting *Underberg v. United States*, 362 F. Supp. 2d 1278, 1283 (D.N.M. 2005)).<sup>11</sup>

Defendants have listed several documents relating to the prescription drug Aduhelm, which is prescribed for the treatment of Alzheimer’s disease.<sup>12</sup> Such documents are wholly irrelevant with regard to this case, in which the jury will decide whether Defendants made false or misleading claims about a dietary supplement product purportedly marketed to persons not suffering from any cognitive disease. *See* Fed. R. Evid. 401.<sup>13</sup> Defendants’ other proposed exhibits relating to the FDA and its laws and guidance similarly have no relevance.<sup>14</sup> As set out in Plaintiffs’ summary judgment opposition and *Daubert* briefs, FDA laws and regulations are irrelevant in an advertising substantiation case brought under the FTC Act (and parallel New York law). (*See* Pls. Opp’n to Defs’ Mot. for Summ. J. (ECF No. 254) at 17 & n.4; Pls. Mem. in Supp. of Their Mot. to Exclude (ECF No. 304) at 10-12; Pls. Reply in Supp. of Their Mot. to Exclude (ECF No. 318) at 11-14.).

Defendants have listed multiple documents relating to their settlement with class-action plaintiffs in the matter of *Collins*.<sup>15</sup> Documents relating to that settlement, however, are not relevant to whether Defendants possessed adequate substantiation for the claims challenged in

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<sup>11</sup> See Defs.’ Exs. DX-402, 416, 422—24 (Defendants’ responses to Plaintiffs’ interrogatories).

<sup>12</sup> *See, e.g.*, Defs.’ Exs. DX-427, 448—49, 473—74 (examples of documents relating to Aduhelm and/or FDA).

<sup>13</sup> Additionally, some of Defendants’ Aduhelm-related documents are newspaper articles (*e.g.*, Defs.’ Ex. DX-427), which are inadmissible hearsay. *See McAllister v. New York City Police Dept.*, 49 F. Supp. 2d 688, 705 n.12 (S.D.N.Y. 1999).

<sup>14</sup> *See, e.g.*, Defs.’ Ex. DX-77.

<sup>15</sup> *See, e.g.*, Defs.’ Exs. DX-414, 417, 421, 428, 430.

this matter. *See* Fed. R. Evid. 401. Nor are such documents relevant to the relief Plaintiffs seek in this case. Though Defendants might argue that the disclaimer the settlement requires for Defendants' advertisements obviates the need for injunctive relief, the issue of whether Defendants' post-settlement advertisements continue to make deceptive claims is a question of fact to be decided by the jury in the instant case. *See Thompson Medical Co. v. FTC, Inc.*, 791 F.2d 189, 194 (D.C. Cir. 1986) (whether a claim has been made is a question of fact).

**XV. PLAINTIFFS' LIST OF INDIVIDUALS AND COMPANIES THAT MIGHT APPEAR AS WITNESSES OR BE REFERRED TO DURING TRIAL**

At trial, Plaintiffs might call as witnesses the following individuals: Mark Underwood, Todd Olson, Kenneth Lerner, Keith Thomsen, William Ducklow, Donya Jackson, Lynne Colbert, Sheya Jabouin, Mary Sano, Ph.D., Janet Wittes, Ph.D., Jeremy Berg, Ph.D., and Peter Malaspina, Ph.D. In addition to the individuals listed above, Plaintiffs might refer to the following individuals or companies: Rosemary Rosso, Serena Viswanathan, Michelle Rusk, J. Howard Beales, Georgetown Economic Services, Cogstate Ltd., U.S. Food and Drug Administration, Custom Biologics, Dakota Miller, Daniel Moran, Michael Beaman, Thomas Dvorak, Erin Adams, Nathan Beaman, Peggy Sivesind, Taylor Gabourie, Amadeus Benitez, Stephanie Hobbins, Mariana Brewster, Kelsey Harter, Robert Risch, Lizzie Malzfeldt, Steven Holmquist, David Merrick, Merrick Wellness, LLC, Tamara Beaman, James Moyer, Jr., Ph.D.,

Norton Milgram, Ph.D., Teri Barr, Janet Liang, Ph.D., Robert Fenili, Ph.D., Paul Pencharz,  
James Lugo, and Cedric Annweiler.

Respectfully submitted,

Dated: November 17, 2022

FEDERAL TRADE COMMISSION

/s/ Andrew Wone

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